

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

IN RE: AREDIA AND ZOMETA)
PRODUCTS LIABILITY LITIGATION) NO. 3:06-md-1760
This Document Relates to Case) JUDGE CAMPBELL
No. 3:06-0550 (White))

MEMORANDUM

Pending before the Court is Defendant's Motion for Summary Judgment (Docket No. 2310). For the reasons stated herein, Defendant's Motion is GRANTED in part and DENIED in part as follows.

FACTS

Plaintiff Cheryl White alleges that Defendant's product, Zometa, caused her deceased husband William White to develop osteonecrosis of the jaw ("ONJ").¹ Plaintiff asserts causes of action for strict liability, negligent design, negligent failure to warn, breach of expressed warranty, and breach of implied warranty.

SUMMARY JUDGMENT

Summary judgment "should be rendered if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). In deciding a motion for summary judgment, the Court must review all the evidence, facts and inferences in the light most favorable to the nonmoving party. *Van Gorder v. Grand Trunk Western Railroad, Inc.*,

¹ Mr. White died of cancer in 2006, and Mrs. White was substituted as his personal representative in this action.

509 F.3d 265, 268 (6th Cir. 2007). In order to defeat a summary judgment motion, the nonmoving party must provide more than a scintilla of evidence; that is, the nonmoving party must present evidence sufficient to permit a reasonable jury to find in its favor. *Van Gorder*, 509 F.3d at 268. Entry of summary judgment is appropriate against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial. *Id.*

CAUSATION

Defendant first asserts that Plaintiff has no admissible proof of medical causation for the reasons asserted in Defendant's Motion for Summary Judgment Based on Failure of General Causation Proof under *Daubert*. The Court has denied that motion.

Defendant also asserts that Plaintiff has no admissible proof of specific medical causation because the Court should exclude the case-specific causation opinions of Plaintiff's retained expert Dr. Najjar and any case-specific causation opinions of Mr. White's treating physicians designated as non-retained experts. The Court has not considered the specific causation testimony of Plaintiff's non-retained experts in this case. However, the Court has denied Defendant's Motion to Exclude the Testimony of Dr. Najjar.

Under California law, which must be applied in this case, the standard for proving causation is expressed as follows:

In a personal injury action causation must be proven within a reasonable medical probability based on competent expert testimony. Mere possibility alone is insufficient to establish a *prima facie* case. That there is a distinction between a reasonable medical "probability" and a medical "possibility" needs little discussion. Although there can be many possible "causes," indeed, an infinite number of circumstances which can produce an injury or disease, a possible cause only becomes "probable" when, in the absence of other reasonable causal explanations, it becomes

more likely than not that the injury was a result of its action. This is the outer limit of inference upon which an issue may be submitted to the jury.

Jones v. Ortho Pharmaceutical Corp., 163 Cal. App. 3d 396, 402-03 (Cal. Ct. App. 1985) (citations omitted); *Avila v. Willits Environmental Remediation Trust*, 2009 WL 1813125 at * 4 (N.D. Cal. June 18, 2009).

Defendant maintains that Plaintiff's expert cannot prove causation unless adequate investigation eliminates all other reasonable causal explanations for Mr. White's injury. In other words, Defendant argues Plaintiff must rule out all other alternative causes. Plaintiff contends that she has adequately shown that Zometa "probably" caused Mr. White's ONJ and she does not have to rule out all other possibilities.

Plaintiff's expert, Dr. Najjar, has testified that he believes with reasonable medical certainty that Plaintiff White's osteonecrosis of the jaw was caused by Zometa. Docket No. 2530-9, p. 75-76 (Najjar 3-17-2009 Deposition, p. 163). The law in California does not require Dr. Najjar to completely rule out all other possible causes. Plaintiff has presented evidence, based upon competent expert testimony within a reasonable medical probability that Zometa caused Mr. White's injury. A jury will have to determine whether to believe Plaintiff's experts or Defendant's experts, but Plaintiff has presented sufficient evidence to survive summary judgment on the causation issue.

FAILURE TO WARN

California follows the "Learned Intermediary Doctrine" with regard to warnings claims and, thus, a manufacturer discharges its duty to warn if it provides adequate warnings to the physician about any known or reasonably knowable dangerous side effects, regardless of whether the warning reaches the patient. *Motus v. Pfizer, Inc.*, 196 F.Supp.2d 984, 990-91 (C.D. Cal. 2001). A plaintiff asserting causes of action based on a failure to warn must prove not only that no warning or an

inadequate warning was given, but also that the inadequacy or absence of the warning caused the plaintiff's injury. *Id.* at 991. Plaintiff must prove that the alleged failure to warn was a "substantial factor" in bringing about the injury. *Id.*

Defendant argues first that its warnings were adequate as a matter of law. For the reasons the Court denied Defendant's Motion for Summary Judgment on the Adequacy of Warnings, this argument fails. There are genuine issues of material fact as to what Defendant knew or should have known when and what warnings would have been reasonably adequate at the time.

With regard to causation, California has not adopted a rebuttable presumption that the physician would have heeded an adequate warning. *Motus*, 196 F.Supp.2d at 995. Thus, Plaintiff has to adduce evidence that Mr. White's treating physicians would have acted differently had Defendant provided an adequate warning about the risk of Zometa. *Id.*; see also *Nix v. Smithkline Beecham Corp.*, 2007 WL 2526402 at * 2 (D. Az. Sept. 5, 2007) (applying California law).

Plaintiff's treating oncologist, Dr. Tanaka, testified that if he had known when he prescribed Zometa to Mr. White what he knows today about ONJ, he would still prescribe it, but with a change in how he prepares the patient for the drug, things like having teeth checked out by a dentist and having a dentist consider an x-ray to make sure the teeth are in good repair. Docket No. 2530-5, p. 39 (Tanaka Feb. 12, 2008 Deposition, p. 146). Under the circumstances of this case, it is sufficient for Plaintiff to survive summary judgment to show that one of Mr. White's treating physicians, not simply the prescriber, would have behaved differently. Given additional knowledge, Plaintiff's oncologist might have still prescribed the drug, but Plaintiff himself and/or Plaintiff's dentist or oral surgeon might have behaved differently. For purposes of summary judgment, there are genuine

issues of material fact as to whether different warnings would have made a difference in either the onset or the extent of Mr. White's ONJ.

NEGLIGENT DESIGN

Under California law, a product is not negligently designed so long as the manufacturer took reasonable precautions in an attempt to design a safe product or otherwise acted as a reasonably prudent manufacturer would have under the circumstances. *Torres v. Taser Int'l, Inc.*, 2008 WL 1944821 at ** 2 (9th Cir. May 5, 2008).

Here, Plaintiff's negligence claim involves numerous issues of fact, as the Court must look at the reasonableness of the behavior, the design and the warnings, and also the required element of causation. For these reasons, Defendant's Motion for Summary Judgment on the negligent design claim is denied.

EXPRESS WARRANTY

In California, to make out a claim for breach of express warranty, a plaintiff must show that the seller (1) made an affirmation of fact or promise or provided a description of its goods; (2) the promise of description formed part of the basis of the bargain; (3) the express warranty was breached; and (4) the breach caused injury to the plaintiff. *Rodarte v. Philip Morris, Inc.*, 2003 WL 23341208 at * 5 (C.D. Cal. June 23, 2003). To state a claim for breach of express warranty, a plaintiff must allege "the exact terms of the warranty." *Id.*

Plaintiff alleges that Novartis made explicit warranties to the general public through the publication of informational materials that "adverse reactions to Zometa are usually mild and transient and similar to those reported for other bisphosphonates." Defendant responds that this language is not a "specific and unequivocal" affirmation of fact or promise, as required under

California law and there is no evidence that either Mr. White or Mr. White's physicians relied upon this language in any event. The Court agrees with Defendant.

Plaintiff has not carried her burden of showing an expressed warranty as required under California law or of any reliance by Mr. White or Mr. White's physicians upon any such warranty as a basis of the bargain in purchasing Zometa. Defendant's Motion for Summary Judgment on Plaintiff's expressed warranty claim is GRANTED, and that claim is DISMISSED.

IMPLIED WARRANTY

In California, a warranty that goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind. Cal. Com. Code § 2314. To be merchantable, goods must, among other things, be adequately contained, packaged, and labeled. *Id.*

Defendant asserts that Plaintiff's implied warranty claim fails because California law requires that the Plaintiff be in privity with the manufacturer in order to bring such a claim. It is true that the general rule in California is that privity of contract is required in an action for breach of either express or implied warranty. *Blanco v. Baxter Healthcare Cop.*, 158 Cal. App. 4th 1039, 1058-59 (Cal. Ct. App. 2008).


As Plaintiff points out, however, there is an exception for drugs. *Arnold v. Dow Chemical Co.*, 110 Cal Rptr. 2d 722, 739 (Cal. Ct. App. 2001); *Gottsdanker v. Cutter Laboratories*, 6 Cal. Rptr. 320, 323 (Cal. Dist. Ct. App. 1960). Where the goods are intended to be and are introduced into the body of a human being, the sale upon which implied warranties are based need not be from the manufacturer to the consumer. *Id.*

As indicated above, there are genuine issues of material fact as to whether Zometa was adequately packaged and labeled. Defendant's Motion for Summary Judgment is denied as to Plaintiff's implied warranty claim.

CONCLUSION

For all these reasons, Defendant's Motion for Summary Judgment (Docket No. 2310) is GRANTED in part and DENIED in part. Plaintiff's expressed warranty claim is DISMISSED.

IT IS SO ORDERED.


TODD J. CAMPBELL
UNITED STATES DISTRICT JUDGE